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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/390,851	09/07/1999	HENRIK PEDERSEN	5655.204-US	7651

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EXAMINER

FRIEND, TOMAS H F

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/390,851

Applicant(s)

PEDERSEN ET AL.

Examiner

Tomas Friend

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-39 and 48-55 is/are pending in the application.
- 4a) Of the above claim(s) 40-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-39 and 48-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

Change of Art Unit Designation

Please note: The Art Unit location of this application in the PTO has changed from Art Unit 1627 to Art Unit 1639. To aid in matching papers to this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Status of the Application

Receipt is acknowledged of a response to an office action with amendment on 23 October 2002 (Paper No. 21).

Status of the Claims

Claims 28-39 and 48-55 are pending and examined on their merits.

Withdrawn Rejections/Objections

1. The objections to the specification and claims 35, 36, and 54 are withdrawn.
2. The rejection of claims 28, 29, 31-33, 48, 49, and 54 under 35 U.S.C. 112, second paragraph, are withdrawn.

Maintained Rejections

The statutory basis for each of the following rejections may be found in a prior office action.

Maintained Rejections – 35 U.S.C. 112, first paragraph

3. Claims 28-39 and 48-55 remain rejected under 35 U.S.C. 112, first paragraph, (scope of enablement) for reasons made of record in Paper No. 19.

Applicants argue that [1] the specification, pages 9, 24, 25, and 27, provides adequate guidance for constructing catalyst-substrate units; [2] pages 18-24 of the specification provide adequate guidance with respect to substrate reloading; [3] pages 33-37 describe selection and isolation of a catalyst of interest; [4] examples 1-9 demonstrate that one skilled in the art can practice the claimed invention commensurate with the scope of the claims; and [5] the amount of experimentation required to practice the claimed method would not be “undue.”

Applicants’ arguments have been fully considered but they are not persuasive. [1] As indicated in the rejection of record, the catalysts encompassed by the claimed invention include metals, organometallic compounds, and enzymes including oxidoreductases such as dehydrogenases, electron transport enzymes, and larger complex catalysts such as replizomes and proteozomes, for example. Page 9 merely states that there is a direct or indirect connection between a catalyst and a substrate. Pages 24, 25, and 27 provide no structural, chemical, or functional guidance with respect to the construction of a catalyst-substrate unit. [2] With regard to substrate loading, pages 18-24 of the specification provide guidance only with respect to RNA polymerase and glycogenase. No guidance is provided for non-enzymatic catalysts or enzymes that, for example, catalyze electron, ion, or molecular transport, or ATP synthesis. [3] Pages 33-37 provide general principles for separation or selection which are generally applicable to the separation or selection of proteins.

[4] Example 1 in the specification involves SNase expressed on phage as the catalyst but excludes method steps of the presently claimed invention that involve substrate reloading. Example 2 provides a brief outline of how glycogenase expressed by phage might be used in place of SNase. Example 3 is a brief outline in broad terms of how a substrate might be attached to an enzyme using a plasmid expression system involving peptide fusions without reference to non-enzyme catalysts or any specific enzyme-substrate pairs actually used for the claimed method. Example 4 provides a general strategy for optimizing the activity of a secreted enzyme with no reference to a particular enzyme-substrate pair. While examples 1-4 provide guidance

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with respect to SNase specifically, the generalization to other enzymes with varying structures, enzymatic activities, and environmental requirements is not enabled by the examples provided. Non-enzyme catalysts such as metals and organometallic catalysts are not exemplified at all.

Examples 5-8 provide examples involving the enzyme catalysts RNaseA and DNA polymerase Klenow fragment expressed on phage particles and deoxyribozymes with ligase activity immobilized on solid supports. In every example, an additional enzyme is required to regenerate substrate from product. No guidance with respect to other means of converting product to substrate is provided. The claimed invention is enabled for the catalysts exemplified in examples 5-8. Example 9 describes the use of His tags for protein purification.

[5] Applicants argue that practicing the full scope of the presently claimed invention would require only routine testing. The scope of the presently claimed invention is not limited to enzymes or ribozymes with structural and functional similarities that would require only routine testing to enable the method of the invention. The specification has provided no guidance with respect to metallic, organometallic, or other inorganic catalysts that catalyze a broad diversity of reactions under a wide variety of conditions. Applying the presently claimed method to inorganic catalysts used for cracking petroleum, for example, would require more than routine testing because applicants have provided no guidance with respect to such a system and that system is not analogous to the ones exemplified in the specification. A similar situation applied to enzymes and ribozymes that catalyze reactions that are not readily adapted to substrate reloading or involve substrates and products that are not easily linked to the enzyme.

New Grounds of Rejection

New Grounds of Rejection – Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-39 and 48-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-38 of copending Application No. 09/395,017. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '017 application claims a system and a method for selecting a catalyst from a library of catalysts in which enzymes attached to a carrier system are covalently linked to substrate through a flexible linker, product is formed from substrate, enzyme-substrate units are reformed, and enzymes are selected for their ability to catalyze the conversion of substrate to product. The carrier system may comprise phage and/or beads. The specification of the '017 application provides examples in which the selection process involves immobilizing product or substrate using affinity methods.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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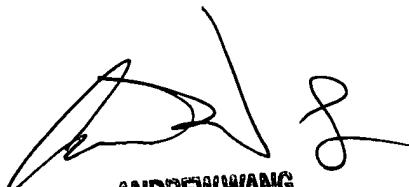
5. This application contains claims 40-47, drawn to an invention nonelected with traverse in Paper No. 18. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner's normal schedule is four, ten-hour days per week including Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
22 January 2003



ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600